

## § 26.64

## 21 CFR Ch. I (4–1–01 Edition)

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

### § 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

### § 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

### § 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the CAB in subpart B may be resubmitted to the other party.

### § 26.67 Suspension of listed conformity assessment bodies.

The following procedures shall apply with regard to the suspension of a conformity assessment body (CAB) listed in subpart B of this part.

(a) A party shall notify the other party of its contestation of the technical competence or compliance of a CAB listed in subpart B of this part and the contesting party's intent to suspend such CAB. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other party;

(b) The CAB shall be given prompt notice by the other party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the parties in the Joint Sectoral Committee described in subpart B of this part. If there is no Joint Sectoral Committee, the contesting party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the CAB shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it

shall normally be carried out in a timely manner by the party in whose territory the body in question is located, but may be carried out jointly by the parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the CAB shall be suspended upon the request of the contesting party;

(f) Upon the suspension of a CAB listed in subpart B of this part, a party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that CAB subsequent to suspension. A party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to suspension, unless a regulatory authority of the party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part; and

(g) The suspension shall remain in effect until agreement has been reached by the parties upon the future status of that body.

**§ 26.68 Withdrawal of listed conformity assessment bodies.**

The following procedures shall apply with regard to the withdrawal from subpart B of this part of a conformity assessment body (CAB):

(a) A party proposing to withdraw a CAB listed in subpart B of this part shall forward its proposal in writing to the other party;

(b) Such CAB shall be promptly notified by the other party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon

confirmation, the withdrawal from the list in subpart B of this part of the CAB shall take effect;

(d) In the event the other party opposes the proposal to withdraw by supporting the technical competence and compliance of the CAB, the CAB shall not at that time be withdrawn from the list of CAB's in subpart B of this part. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the CAB may be resubmitted to the other party; and

(e) Subsequent to the withdrawal of a CAB listed in subpart B of this part, a party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to withdrawal, unless a regulatory authority of the party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part.

**§ 26.69 Monitoring of conformity assessment bodies.**

The following shall apply with regard to the monitoring of conformity assessment bodies (CAB's) listed in subpart B of this part:

(a) Designating authorities shall assure that their CAB's listed in subpart B of this part are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in subpart B of this part. In this regard, designating authorities shall maintain, or cause to maintain, ongoing surveillance over their CAB's by means of regular audit or assessment;

(b) The parties undertake to compare methods used to verify that the CAB's listed in subpart B of this part comply with the relevant requirements of subpart B of this part. Existing systems for the evaluation of CAB's may be used as part of such comparison procedures;

(c) Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both